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TISSUE CONNECTOR APPARATUS AND METHODS

FIELD OF THE INVENTION

The present invention relates to instruments and methods for connecting body tissues, tissue and prostheses, tissue and graft or any combination thereof.

BACKGROUND OF THE INVENTION

Minimally invasive surgery has allowed physicians to carry out many surgical procedures with less pain and disability than conventional, open surgery. In performing minimally invasive surgery, the surgeon makes a number of small incisions through the body wall to obtain access to the tissues requiring treatment. Typically, a trocar, which is a pointed, piercing device, is delivered into the body with a cannula. After the trocar pierces the abdominal or thoracic wall, it is removed and the cannula is left with one end in the body cavity, where the operation is to take place, and the other end opening to the outside. A cannula has a small inside diameter, typically 5-10 millimeters, and sometimes up to as much as 20 millimeters. A number of such cannulas are inserted for any given operation.

A viewing instrument, typically including a miniature video camera or optical telescope, is inserted through one of these cannulas and a variety of surgical instruments and refractors are inserted through others. The image provided by the viewing device may be displayed on a video screen or television monitor, affording the surgeon enhanced visual control over the instruments. Because a commonly used viewing instrument is called an "endoscope," this type of surgery is often referred to as "endoscopic surgery." In the abdomen, endoscopic procedures are commonly referred to as laparoscopic surgery, and in the chest, as thoracoscopic surgery. Abdominal procedures may take place either

inside the abdominal cavity (in the intraperitoneal space) or in a space created behind the abdominal cavity (in the retroperitoneal space). The retroperitoneal space is particularly useful for operations on the aorta and spine, or abdominal wall hernia.

Minimally invasive surgery has virtually replaced open surgical techniques for operations such as cholecystectomy and anti-reflux surgery of the esophagus and stomach. This has not occurred in either peripheral vascular surgery or cardiovascular surgery. An important type of vascular surgery is to replace or bypass a diseased, occluded or injured artery. Arterial replacement or bypass grafting has been performed for many years using open surgical techniques and a variety of prosthetic grafts. These grafts are manufactured as fabrics (often from DACRON® (polyester fibers) or TEFLON® (fluorocarbon fibers)) or are prepared as autografts (from the patient's own tissues) or heterografts (from the tissues of animals) or a combination of tissues, semi-synthetic tissues and or alloplastic materials. A graft can be joined to the involved artery in a number of different positions, including end-to-end, end-to-side, and side-to-side. This attachment between artery and graft is known as an anastomosis. Constructing an arterial anastomosis is technically challenging for a surgeon in open surgical procedures, and is almost a technical impossibility using minimally invasive techniques.

Many factors contribute to the difficulty of performing arterial replacement or bypass grafting. See generally, Wylie, Edwin J. et al., Manual of Vascular Surgery, (Springer-Verlag New York), 1980. One such factor is that the tissues to be joined must be precisely aligned with respect to each other to ensure the integrity and patency of the anastomosis. If one of the tissues is affixed too close to its edge, the suture can rip through the tissue and impair both the tissue and the anastomosis. Another factor is that, even after the tissues are properly aligned, it is difficult and time consuming to pass the needle through the tissues, form the knot in the suture material, and ensure that the suture material does not become tangled. These difficulties are exacerbated by the small size of the artery and graft. The arteries subject to peripheral vascular and cardiovascular surgery

typically range in diameter from several millimeters to several centimeters. A graft is typically about the same size as the artery to which it is being attached. Another factor contributing to the difficulty of such procedures is the limited time available to complete the procedure. The time the surgeon has to complete an arterial replacement or bypass graft is limited because there is no blood flowing through the artery while the procedure is being done. If blood flow is not promptly restored, sometimes in as little as thirty minutes, the tissue the artery supplies may experience significant damage, or even death (tissue necrosis). In addition, arterial replacement or bypass grafting is made more difficult by the need to accurately place and space many sutures to achieve a permanent hemostatic seal. Precise placement and spacing of sutures is also required to achieve an anastomosis with long-term patency.

Highly trained and experienced surgeons are able to perform arterial replacement and bypass grafting in open surgery using conventional sutures and suturing techniques. A suture has a suture needle that is attached or "swedged on" to a long, trailing suture material. The needle must be precisely controlled and accurately placed through both the graft and artery. The trailing suture material must be held with proper tension to keep the graft and artery together, and must be carefully manipulated to prevent the suture material from tangling. In open surgery, these maneuvers can usually be accomplished within the necessary time frame, thus avoiding the subsequent tissue damage (or tissue death) that can result from prolonged occlusion of arterial blood flow.

A parachuting technique may be used to align the graft with the artery in an end-to-side anastomosis procedure. One or multiple sutures are attached to the graft and artery and are used to pull or "parachute" the graft vessel into alignment with an opening formed in a sidewall of the artery. A drawback to this procedure is the difficulty in preventing the suture from tangling and the time and surgical skill required to tie individual knots when using multiple sutures. Due to space requirements, this procedure is generally limited to open surgery techniques.

The difficulty of suturing a graft to an artery using minimally invasive surgical techniques has effectively prevented the safe use of this technology in

both peripheral vascular and cardiovascular surgical procedures. When a minimally invasive procedure is done in the abdominal cavity, the retroperitoneal space, or chest, the space in which the operation is performed is more limited, and the exposure to the involved organs is more restricted, than with open surgery. Moreover, in a minimally invasive procedure, the instruments used to assist with the operation are passed into the surgical field through cannulas. When manipulating instruments through cannulas, it is extremely difficult to position tissues in their proper alignment with respect to each other, pass a needle through the tissues, form a knot in the suture material once the tissues are aligned, and prevent the suture material from becoming tangled. Therefore, although there have been isolated reports of vascular anastomoses being formed by minimally invasive surgery, no system has been provided for wide-spread surgical use which would allow such procedures to be performed safely within the prescribed time limits.

As explained above, anastomoses are commonly formed in open surgery by suturing together the tissues to be joined. However, one known system for applying a clip around tissues to be joined in an anastomosis is disclosed in a brochure entitled, "VCS Clip Applier System", published in 1995 by Auto Suture Company, a Division of U.S. Surgical Corporation. A clip is applied by applying an instrument about the tissue in a nonpenetrating manner, i.e., the clip does not penetrate through the tissues, but rather is clamped down around the tissues. As previously explained, it is imperative in forming an anastomosis that tissues to be joined are properly aligned with respect to each other. The disclosed VCS clip applier has no means for positioning tissues. Before the clip can be applied, the tissues must first be properly positioned with respect to each other, for example by skewering the tissues with a needle as discussed above in common suturing techniques or with forceps to bring the tissues together. It is extremely difficult to perform such positioning techniques in minimally invasive procedures.

Therefore, there is currently a need for other tissue connecting systems.

SUMMARY OF THE INVENTION

The present invention involves apparatus and methods for connecting material, at least one of which is tissue. The invention may, for example, be used to secure one vessel to another, such as in a vascular anastomosis.

According to one aspect of the invention, a tissue connector assembly is provided comprising a surgical fastener, such as a surgical clip, a first tissue piercing member and a second tissue piercing member. The fastener may be adapted to assume a loop configuration. The fastener has a first end portion and a second end portion. The first tissue piercing member is coupled to the first end portion and the second tissue piercing member is coupled to the second end portion. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer walls of material, such as tissue, which may eliminate or minimize the possibility of dislodging material from the inner wall of a vessel, for example.

According to another aspect of the invention, a flexible member, such as a suture, may be provided between at least one piercing member and the fastener to facilitate threading the fastener and/or "parachute" techniques, for example.

According to another aspect of the invention, synchronized piercing member release mechanisms may be provided. In one embodiment, the tissue connector assembly may include a first coupling, which couples the first tissue piercing member and first end portion of the surgical fastener, and a second coupling, which couples the surgical fastener second end portion and second piercing member. The first coupling releases the other coupling in response to releasing the first coupling. According to one aspect of this embodiment, multiple tissue piercing members may be decoupled from the surgical fastener with one release actuator. Accordng to another aspect, the piercing members may be decoupled essentially simultaneously.

The above is a brief description of some deficiencies in the prior art and advantages of the present invention. Other features, advantages, and embodiments of the invention will be apparent to those skilled in the art from the following description, accompanying drawings, and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective of a tissue connector assembly constructed in accordance with the principles of the present invention;

Fig. 2A is a partial sectional view illustrating an alternate construction of flexible member 18 of Fig. 1;

Fig. 2B is a partial sectional view illustrating yet another construction of flexible member 18 of Fig. 1;

Figs. 3A, 3B and 3C show a fastener which can be used with the tissue connector assembly of Fig. 1, where Fig. 3A is a top view of the fastener in a closed position, Fig. 3B is a side view of the fastener of Fig. 3A, and Fig. 3C is an enlarged view of the fastener of Fig. 3A in an open position;

Fig. 4 is a top view of another fastener configuration, which can be used with the tissue connector assembly of Fig. 1;

Figs. 5A and 5B show yet another fastener configuration which can be used with the tissue connector assembly of Fig. 1, where Fig. 5A shows the fastener in a closed position and Fig. 5B is a side view of the fastener of Fig. 5A;

Fig. 6 is top view of yet a further configuration of a fastener that can be used with the tissue connector assembly of Fig. 1 with the fastener in a closed position;

Figs. 7A, 7B and 7C illustrate a release mechanism which can be used with any of the fasteners described above and the tissue connector assembly of Fig. 1, where Fig 7A shows the restraining device in cross-section and in a locked position, Fig. 7B is a transverse cross-sectional view of the restraining device taken in a plane along line 7B--7B of Fig. 7A , and Fig. 7C is a cross-sectional view of the restraining device of Fig. 7A in an unlocked position;

Figs. 8A, 8B and 8C illustrate another release mechanism which can be used with any of the fasteners described above and the tissue connector assembly of Fig. 1, where Fig 8A shows the restraining device in cross-section and in a locked position, Fig. 8B is a transverse cross-sectional view of the restraining

device taken in a plane along line 8B--8B of Fig. 8A, and Fig. 8C is a cross-sectional view of the restraining device of Fig. 8A in an unlocked position;

Figs. 9A-9E illustrates yet another release mechanism which can be used with any of the fasteners described above, where Fig. 9A shows a perspective view of the retaining device coupled with a fastener, Fig. 9B is a sectional view of the retaining device of Fig. 9A, Fig. 9C is a transverse cross-sectional view of the restraining device taken along line 9C-9C in Fig. 9B, Figs. 9D and 9E are perspective and end views of the restraining device, respectively, showing the device depressed for release of the fastener; and Fig. 9F shows the retaining device of Fig. 9A with an adapter for coupling to the other end of the fastener;

Figs. 10A-10C show a synchronized fastener release system, where Figs. 10A and 10C are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 10B is a sectional view taken along lines 10B-10B in Fig. 10A;

Figs. 10 D-10F show another synchronized fastener release system, where Figs. 10D and 10E are partial sectional views of the system in a coupled and decoupled state, respectfully, and Fig. 10F is a transverse cross-sectional view taken along line 10F-10F in Fig. 10E;

Figs. 11A and 11B are partial sectional views of another piercing member and/or suture release mechanism in a coupled and decoupled state, respectfully;

Figs. 12A and 12B are partial sectional views of a further piercing member and/or suture release mechanism in a coupled and decoupled state, respectfully;

Figs. 13A and 13B are partial sectional views of yet another piercing member and/or suture release mechanism in a coupled and decoupled state, respectfully;

Fig. 14A is a front view of a another embodiment of a tissue connector assembly of the present invention;

Fig. 14B is a sectional view of a piercing member and release mechanism combination, which can be used in the embodiment, illustrated in Fig. 14A;

Fig. 15 is a front view of a lateral tissue connector, which can be used in conjunction with any of the assemblies described above;

Figs. 16A-16D diagrammatically illustrate a method of aligning and connecting graft and target vessels with the tissue connector assembly of Fig. 1, where Fig. 16A shows two such tissue connector assemblies threaded through a graft and target vessel, Fig. 16B shows a further step in connecting the graft and target vessel with the tissue connector assembly fastener is positioned in the target vessel, Fig. 16C shows yet a further step where the graft has been brought into position over the opening formed in the target vessel and the tissue connector assembly fastener positioned through the walls of the graft and target vessel and Fig. 16D shows the fasteners released from the tissue connector assembly of Fig. 1 and securing the graft and target vessel together with additional laterally disposed fasteners;

Fig. 16E is a partial sectional view of the graft and target vessels with the tissue connector assembly fasteners of Fig. 1 in place prior to placement of additional lateral fasteners; and

Fig. 16F is an enlarged view of the tissue connection within line 16F of Fig. 16E.

Corresponding reference characters indicate corresponding elements throughout the drawings.

DESCRIPTION OF THE INVENTION

The present invention generally involves methods and devices for manipulating, aligning and/or connecting tissues, tissue and prosthesis, tissue and graft, or any combination thereof. As used herein, the term graft includes any of the following: homografts, autologous grafts, xenografts, allografts, alloplastic materials, and combinations of the foregoing. Tissue connector assemblies are disclosed, which, for example, may be used in vascular surgery to replace or bypass a diseased, occluded, or injured artery by connecting a graft vessel to a coronary artery or vein in an anastomosis as shown in Figs. 16A-F. Assemblies constructed in accordance with the invention may be used in open surgical

procedures or in minimally invasive or endoscopic procedures for attaching tissue located in the chest, abdominal cavity, or retroperitoneal space. It should be understood, however, that these examples are provided for illustration and are not intended to limit the scope of the invention.

Tissue connecting assemblies and methods are disclosed in copending U.S. Patent Application Serial Nos. 09/089,884 and 09/090,305, both entitled Tissue Connector Apparatus and Methods and having a filing date of June 3, 1998. The entirety of the disclosures of the cited '884 and '305 applications is hereby incorporated herein. One aspect of the present invention is the provision of multiple tissue piercing members. More specifically, tissue connecting assemblies constructed according to the present invention generally include a plurality of tissue piercing or penetrating members coupled to a surgical fastener. The multiple piercing member construction facilitates threading ends of the assembly from inner to outer wall(s) of material, such as tissue, which may eliminate or minimize the possibly of dislodging material, such as plaque, from the inner wall of calcified arteries, for example, as will become more apparent from the description provided below. In a preferred embodiment, two piercing members, each of which may comprise a needle, are releaseably coupled to a fastener. One or both of the piercing members may be attached to a flexible member, such as a suture, which in turn is releaseably coupled to the fastener. Double and single flexible member embodiments are illustrated in Figs. 1 and 14, respectively. The coupling between the flexible member (and, thus, the piercing member) and the fastener may be constructed to actuate closure of the fastener upon release of the flexible member (or piercing member). For example, the coupling may hold a compression spring (which is positioned around a fastener) in a compressed state to brace the fastener open and releaseably lock or secure the fastener to the flexible member (or piercing member).

Fig. 1 illustrates one embodiment of a tissue connector assembly in accordance with the present invention. Referring to Fig. 1, a tissue connector assembly 11, which generally comprises tissue piercing or penetrating members 16 and 17, flexible members 18 and 19, and a fastener 20 (e.g., a surgical clip) is

shown. A restraining device, generally indicated at 24 and comprising a spring (or coil) 26 and a locking device (or coupling member) generally indicated at 28, is connected to fastener 20 for holding the fastener in a deformed or open configuration as will be further described below. Although a particular fastener and accompanying restraining device is shown in Fig. 1, it should be understood that any suitable fastener can be used, including but not limited to the alternate fastener configurations described below. For example, the fastener may be a plastically deformable clip or may comprise two or more parts, at least one of which is movable relative to the other part, such as with a hinged clip. Further, other piercing member release mechanisms can be used with or without restraining devices depending on the fastener construction.

Each of penetrating or piercing members 16 and 17 may be in the form of a needle (such as a 7-0 or 8-0 needle) having a sharp pointed tip (30 or 31) at its distal end for penetrating tissue. Members 16 and 17 may be bent as shown in Fig. 1, for example. The diameter of at least a portion of each of members 16 and 17 is preferably greater than the diameter of the respective flexible members (18 and 19), coupled thereto so that the flexible members can easily be pulled through an opening formed in the tissue (or other material) by the needle. The distal ends of the members 16 and 17 are preferably rigid to facilitate penetration of tissue. The remaining length of members 16 and 17 may be rigid or flexible to facilitate movement of the needle through the tissue as further described below. Tips 30 and/or 31 may have various configurations and may, for example, be conical, tapered, or grounded to attain a three or four facet tip. Members 16 and 17 may be made from stainless steel or any other suitable material, such as a polymeric material. It is to be understood that members 16 and 17 may have a shape or radius of curvature other than the one shown, without departing from the scope of the invention. Members 16 and 17 may also be integrally formed with the flexible member 18 (e.g., both piercing member and flexible member formed of the same material).

The flexible members 18 and 19 may be in the form of a suture formed from conventional filament material, metal alloy, such as nitinol, polymeric

material, or any other suitable material. The material may be non-stretchable or stretchable, solid or hollow (as shown, for example, in Figs. 2A and 2B), and have various cross-sectional diameters. The flexible members or sutures may have a cross-sectional diameter of .003 inch, for example. The diameter and length of the suture will vary depending on the specific application. The sutures may be attached to the piercing members 16 and 17, respectively, by crimping or swaging the piercing member or needle onto the suture, gluing the suture to the piercing member or needle, or any other suitable attachment method. Flexible members 18 and 19 may have cross-sectional shapes other than the one shown herein and may have other constructions as well.

Referring to Fig. 2A, an alternate flexible member construction is shown. Flexible member 18' generally comprises a flexible filament 14, which may be in the form of a metal wire, and tube or sleeve 15, which may be in the form of a hollow suture. Tube 15 surrounds filament 14 with one end of the filament 14 secured to piercing member 16 and its other end secured to coupling 28 with glue, for example. The filament may provide kink resistance and pull strength (to minimize or eliminate stretch), and is especially advantageous when using very thin material for tube 15. Tube 15 may, for example, comprise polymeric materials such as polyurethane or polyester. It is noted that at least the portions of the tube adjacent to needle 16 and coupling 28 have the same diameter as the portions of the coupling and needle adjacent thereto. This eliminates the need for the tapered portions 2 and 3 shown in Fig. 1 or other transition sections to minimize or eliminate the step between the flexible member and needle and/or the flexible member and the coupling. Of course, the diameter of the entire flexible member may be the same as that of the coupling and the portion of the needle adjacent to the flexible member as indicated in Fig. 2A. It also should be apparent from the foregoing that the construction of flexible member 18' may be substituted for flexible member 19.

Referring to Fig. 2B, another hollow flexible member construction is shown. Flexible member 18'' comprises tube or sleeve 15, which may be in the form of a hollow suture. Tube 15 is secured to piercing member or needle 16 and

coupling 28 through posts or anchors 4, which in turn, are secured to piercing member or needle 16 and coupling 28. The relative dimensions of tube 15 as compared to needle 16 and coupling 28 may be the same as those describe in connection with Fig. 2A for the same reasons. Further, flexible member 18'' may be substituted for flexible member 19 as well.

Referring to Figs. 3-6, fasteners, which were shown in copending U.S. Patent Application Serial Nos. 09/089,884 and 09/090,305 and which may be used in the present invention, first will be described. Referring to Figs. 3A-C, one embodiment of a fastener (e.g., fastener 20) comprises a deformable wire 34 made of a shape memory alloy. A nickel titanium (nitinol) based alloy may be used, for example. The nitinol may include additional elements which affect the yield strength of the material or the temperature at which particular pseudoelastic or shape transformation characteristics occur. The transformation temperature may be defined as the temperature at which a shape memory alloy finishes transforming from martensite to austenite upon heating (i.e., A_f temperature). The shape memory alloy preferably exhibits pseudoelastic (e.g., superelastic) behavior when deformed at a temperature slightly above its transformation temperature. At least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration. When the wire is positioned within the tissue in its undeformed configuration, a residual stress is present to maintain the tissue tightly together (see e.g., Fig. 16F). In order for the pseudoelastic wire 34 to retain sufficient compression force in its undeformed configuration, the wire should not be stressed past its yield point in its deformed configuration to allow complete recovery of the wire to its undeformed configuration. The shape memory alloy is preferably selected with a transformation temperature suitable for use with a stopped heart condition where cold cardioplegia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used, as is well known by those skilled in the art.

The cross-sectional diameter of wire 34 and length of the wire will vary depending on the specific application. The diameter "d" of wire 34 may be, for example, between 0.001 and 0.015 inch. For coronary bypass applications, the diameter is preferably between 0.001 and 0.008 inch with a diameter "D" of the loop (Fig. 3A) being between 0.0125 and 0.0875 inch. As shown in Fig. 3A and 3B, wire 34 may have a circular cross-sectional shape and a generally ring or loop shaped configuration when in a closed position. The diameter "D" of the loop of the fastener 20 (with coil 26, which may be platinum) in its closed position is preferably sized to prevent movement between adjacent tissues. It is to be understood, however, that the wire may have other cross-sectional shapes such as rectangular, or may be formed from multiple strands without departing from the scope of the invention.

One end of wire 34, which may be referred to as the proximal end of wire 34, may include an enlarged portion 36 having a cross-sectional area greater than the cross-sectional area of the wire to resist the coil from passing thereover. The enlarged portion 36 also may be provided to cooperate with a release mechanism as will be discussed in more detail below. Enlarged portion 36 may be formed by attaching a member to the end of wire 34 by welding, gluing or other suitable attachment means or may be formed integrally with the wire by deforming the end of the wire. The other end of wire 34, which may be referred to as the distal end of wire 34, also may include an enlarged portion 38 for engagement with a restraining device, such as restraining device 24 (see. e.g., Fig. 1), or a locking device or release mechanism, such as release mechanism 28 (see e.g., Fig. 1), as further described below. The enlarged portion 38 may be formed by deforming the end of the wire 34 by swaging or arc welding, or attaching an enlarged portion to the end of the wire by welding, swaging, or other suitable means. Although enlarged portions 36 and 38 are shown with spherical and cylindrical configurations, other configurations or configuration combinations can be used.

For example, both enlarged portions may be spherical or cylindrical, or portion 36 may be cylindrical and portion 38 spherical.

Referring to Figs. 3A-C, fastener 20 is shown in open and closed configurations. When wire 34 is in an undeformed or closed configuration, the fastener is closed (as shown in Figs. 3A and 3B) for keeping or connecting tissue together, and when wire 34 is in a deformed or open configuration, the fastener is open (as shown in Fig. 3C) for insertion of the wire into tissue. As discussed above, wire 34 is in its closed configuration when in a relaxed state. Wire 34 is preferably not deformed past its yield point in its open position. Accordingly, it may have a U-shaped configuration in its open position to facilitate insertion of the wire through the tissue. It is to be understood that U-shaped configuration may be alternatively substituted by an equivalent structure such as C-shaped, V-shaped, J-shaped, and other similarly shaped configurations. Wire 34 is moved from its closed position to its open position by a restraining device, as further described below. When in its closed position, wire 34 forms a loop with the ends of the wire in a generally side-by-side or overlapping orientation (Fig. 3B).

Wire 34 may be formed in the above described shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-500 degrees Celsius for approximately 5 to 30 minutes. Wire 34 is then air quenched at room temperature. The mandrel may have a constant diameter or may be conical in shape.

Referring to Fig. 4, an alternate configuration of fastener 20 in its closed position is shown, and generally indicated with reference numeral 40. Fastener 40 forms a spiral configuration in its closed position for trapping the tissue within a loop formed by the spiral. In its open position, the fastener 40 is configured to form less than a full 360 degree turn, and may be made to have an open position as shown in Fig. 3C, for example.

Referring to Figs. 5A and 5B, another configuration of fastener 20 is shown in its closed position, and is generally designated with reference numeral 41. Fastener 41 is formed in a spiral about a central longitudinal axis A. As shown in Fig. 5B, fastener 41 has a generally conical shape along the longitudinal

axis A, with a decreasing diameter as the radius of curvature of fastener 41 decreases. Fastener 41 has an inner end portion 45 and an outer end portion 47, with the enlarged portion 38 of the wire being disposed at the outer end portion for engagement with the restraining device 24 as shown, for example, in Fig. 3C.

Referring to Fig. 6, a modification of fastener 41 is shown, and generally indicated with reference numeral 43. Fastener 43 is similar to fastener 41 described above, except that enlarged portion 38, which is adapted for engaging a restraining device or releasable locking mechanism, is positioned at the inner end portion 45 of the fastener. Placement of restraining device 24 at the inner end portion 45 of fastener 43 increases the compression force of the wire in its undeformed position on the tissue and decreases the surface area of the fastener exposed to blood flow.

It is to be understood that the fasteners may have undeformed or deformed configurations different than those shown herein without departing from the scope of the invention. In addition, a locking clip (not shown) may also be attached to connect the ends of the fastener (such as fastener 20, 40, 41, 43) when the fastener is in its closed position to prevent possible opening of the fastener over time. The locking clip may also be integrally formed with one end of the fastener.

As shown in Fig. 3C, wire 34 is surrounded by spring or coil 26 which, along with the locking device 28, restrains the wire in its deformed configuration. Coil 26 comprises a helical wire forming a plurality of loops which define a longitudinal opening 44 for receiving the shape memory alloy wire 34. Coil 26 may be formed from a platinum alloy wire having a cross-sectional diameter of approximately 0.0005-0.005 inch, for example. The helical wire may have other cross-sectional shapes and be formed of different materials. Coil 26 is preferably sized so that when in its free (uncompressed state) it extends the length of wire 34 with one end adjacent the enlarged portion 36 at the proximal end of the wire and the other end adjacent enlarged portion 38 at the distal end of the wire. It is to be understood that the coil may not extend the full length of the wire. For example, a flange or similar device may be provided on an intermediate portion of wire 34 to limit movement of the coil along the length of the wire.

When coil 26 is in its free state (with the wire in its undeformed configuration), loops of the coil are generally spaced from one another and do not exert any significant force on the wire 34 (Figs. 3A and 3B). When the coil 26 is compressed (with the wire 34 in its deformed configuration), loops of the coil on the inner portion 46 of the coil are squeezed together with a tight pitch so that the loops are contiguous with one another while loops on the outer portion 48 of the coil are spaced from one another (Fig. 3C). This is due to the compressed inner arc length of coil 26 and the expanded outer arc length of the coil. The compression of the loops on the inner portion 46 of coil 26 exerts a force on the inner side of wire 34 which forces the wire to spread open (i.e., tends to straighten the wire from its closed configuration to its open configuration). The end of coil 26 adjacent enlarged portion 36 is held in a fixed position relative to wire 34. The opposite end of coil 26 is free to move along wire 34 and is held in place when the coil is in its compressed position by locking device 28. It should be understood, however, that a coil (not shown) having sufficient stiffness, for example, may be used where adjacent loops do not contact one another when the coil is compressed to force wire 34 into an open position.

Referring to Figs. 7A-7C, one embodiment of a releaseable locking device or release mechanism, which is disclosed in U.S. Patent Application Serial Nos. 09/089,884 and 09/090,305, is shown. Releaseable locking device 28a is adapted for releaseably coupling a fastener (such as any of the fasteners shown in Figs. 3-6) to a flexible member (such as flexible member 18, 18' or 18'') is shown and generally designated with reference numeral 28a. Release mechanism 28a comprises a flexible tubular member 50 having a distal end portion 52 and is shown with tapered section or sleeve 2, which in turn is coupled to the flexible member. Tapered section or sleeve 2, which provides a transition between the flexible member and fastener for insertion of the fastener through tissue, may be a separate member coupled to tubular member 50 or be formed integrally therewith. Tubular member 50 further includes a proximal end portion 54 releasably attached to wire 34. In this manner, release mechanism 28a releaseably couples the flexible member and needle to the surgical fastener such as fastener 20. In

addition to releasably coupling the flexible member and needle to the fastener, the locking device or release mechanism compresses coil 26 to bias the fastener or surgical clip 20 in its open configuration. facilitate insertion of the locking device 28 through tissue. Although a straight tapered section is shown, it may be curved as well. Tapered portion 2 may be formed from a metal alloy such as stainless steel or a suitable polymeric material and may be solid or in the form of a sleeve as noted above. Generally, tapered section 2 gradually diminishes in diameter to provide a smooth, non-stepped transition between the relatively small diameter of the flexible member to the larger diameter of locking device such as locking device 28a. The flexible member such as flexible member 18 may be swaged into the tapered section, or a heat shrink plastic covering may hold the flexible member in place. The locking device may also be curved.

Tubular member 50 is movable between a locked position (Figs. 7A and 7B) for holding coil 26 in its compressed position and wire 34 in its deformed position, and an unlocked position (Fig. 7C) for inserting or releasing the wire and coil. Referring to Figs. 7B and 7C, three slots 58 are shown formed in tubular member 50 extending from the proximal end 54 of the member and along at least a portion of the member. Slots 58 are provided to allow the proximal end 54 of tubular member 50 to open for insertion and removal of the wire 34. It is to be understood that the number of slots 58 and configuration of the slots may vary, or tubular member 50 may be formed to allow expansion of proximal end 54 without the use of slots.

Proximal end 54 of tubular member 50 includes a bore 62 having a diameter slightly greater than the outer diameter "d" of wire 34, but smaller than the diameter of enlarged portion 38 at the distal end of the wire and the outer diameter of the coil 26. Bore 62 extends into a cavity 64 sized for receiving the enlarged portion 38 of wire 34. Tubular member 50 may be described as having an annular flange 61 for releasably securing enlarged portion 38. As shown in Fig. 7C, upon application of an inwardly directed radial squeezing force on the tubular member 50 proximal end 54 of the tubular member is opened to allow for insertion or removal of wire 34. When the force is released, the tubular member

50 moves back to its locked position and securely holds wire 34 in place and compresses the coil 26 as shown in Fig. 7A. A disc 51 may be inserted into tubular member 50 to act as a fulcrum and cause the proximal end 54 of the tubular member to open. Alternatively, disc 51 may be integrally formed with tubular member 50. As shown in Fig. 7A, the length ℓ of the bore 62 or flange 61 determines the amount of compression of the coil, which in turn determines the amount of deformation of wire 34. The greater the length ℓ of bore 62, the greater the compression of coil 26 and the more straightening of wire 34 will undergo. The compression of coil 26 is preferably limited so that wire 34 is not stressed beyond its yield point. This allows wire 34 to revert back to its original undeformed configuration and apply sufficient pressure to hold the connected tissue together.

Figs. 8A, 8B and 8C illustrate another release mechanism which is generally designated with reference numeral 28b. Figs. 8A and 8B show the release mechanism in a locked position, and Fig. 8C shows the release mechanism in an unlocked position. Release mechanism 28b comprises a tubular member 80, which has proximal and distal ends 88 and 89, respectively. Tubular member 80 further includes bore 82 formed therein and a cavity or recess 84 extending radially outward from bore 82 into the tubular member. Recess 84 is configured to receive enlarged portion 38 or wire 34 as best illustrated in Fig. 8A. Recess 84 and bore 82 form an annular flange 86, which has an inner diameter less than that of enlarged portion 38 and, thus, resists removal of the enlarged portion. In the embodiment shown in Fig. 8A-C, three slots 87 are formed in tubular member 80 as in the embodiment shown in Figs. 7A-C. The slots extend longitudinally from the proximal end 88 of tubular member 80 and form fingers 81, which radially expand and release wire 34 upon radial compression of the tubular member as shown in Fig. 8C and as described above in connection with release mechanism 28a. In this embodiment, however, enlarged portion 38 forms a fulcrum. Although three equiangularly spaced slots, which extend parallel to the longitudinal axis are shown as in release mechanism 28a, the number and

configuration of the slots may vary, or the tubular member may be formed to allow expansion of the proximal end portion without the use of slots. A tapered section 2 also may be provided as described above in connection with release mechanism 28a.

Figs. 9A-9E illustrate yet another release mechanism which is disclosed in U.S. Patent Application Serial No. _________ (attorney docket no. 38840-20007.00) entitled Tissue Connector Apparatus With Cable Release and filed on even date herewith. The release mechanism is generally indicated with reference numeral 28c in Figs. 9A-9E where Figs. 9A-C show the mechanism coupled with a fastener, and Figs. 9D and 9E show the release mechanism depressed for release of the fastener. Locking device or release mechanism 28c comprises a plurality of substantially rigid strands, preferably wires 106, arranged substantially parallel to one another and circularly about a longitudinal axis of the aligned strands, to form a tube-like configuration, as can be seen in the cross-sectional view of Fig. 9C and the perspective view in Fig. 9A. Alternatively, strands 106 may be cables or some other substantially rigid strand elements arranged in the same manner as the wires shown in Figure 9C. Upon arrangement into the circular configuration, the hidden end portions 106a of the strands are coupled to tapered section 2, which is coupled to a piercing member or needle through a flexible member such as flexible member 18.

Preferably, a rod 162 extends from tapered section 2 to facilitate fixation of the strands thereto. The coupling of the strands to tapered section 2 is preferably accomplished by gluing or soldering to rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, rod 162 is preferably glued, soldered or threaded into the needle or transition element. In an alternate arrangement, the flexible member may extend through tapered section 2 and form a substitute structure for rod 162. This may be preferred when the flexible member is a metal wire.

The end portions 106b of the strands in the vicinity of the fastener strands include notches 109 which are formed into the strands to a depth equal to

approximately half the diameter of the strand 106. When the strands are arranged in the circular configuration described above, the notches 109 form a chamber 108 configured for receiving and holding enlarged portion 38. Although enlarged portion 38 is shown as having a spherical shape, it may have other shapes including a barrel shape, or other shape that may be easily grasped and easily released. The notches are preferably placed about .015" from the free ends of the strands, but this distance, of course, can be modified, depending upon the amount of compression of spring 26 that is desired when ball 38 is inserted into and held by notches 109.

After placement of ball 38 within chamber 108 formed by notches 109, a shrink wrap layer, preferably a shrink tubing 110 may be provided over at least free end portions 106b of wires or strands 106, and the tubing heated to compress against strands 106 and hold them in place against ball 38, preferably symmetrically against ball 38. Together, tubing 110 and strands 106 effectively hold ball 38 captive within notches 109. Alternatively, other plastic or elastic restraining members may be mounted around the distal portions of the wires or strands to aid in maintaining them in place, preferably symmetrically against ball 38. Still further, strand members may be designed with an elastic spring force sufficient to maintain notches 109 in place with sufficient force to maintain the ball 38 captive therein under the tensile forces normally experienced during a suturing procedure. Although a seven strand embodiment is shown, it should be understood that fewer or more than seven strands may be used. The number of strands may vary depending on, for example, the size of the clip or the size of the strands. Typically, the number of strands may range from two to ten. In a coronary anastomosis, the number of strands preferably will range from five to seven although other numbers may be used.

In assembling, enlarged portion 38 of wire 34 is placed in chamber 108. Tubing 110 is wrapped around at least a portion of the strands (as shown in the drawings) and heated to maintain enlarged portion 38 captive within the cavity formed by the strands. Compression coil or spring 26 is slid over wire 34 and compressed against portions 106b such that the fastener is in its open

configuration. Enlarged portion 36 may then be formed or attached to wire 34 to maintain the fastener in its open configuration.

Release mechanism 28c is movable between a locked position (Figs. 9A-9c) and an unlocked position (Figs. 9E and 9F). In the locked position the ball 38 is held within notches 109 and consequently, coil 26 is held in its compressed position, thereby maintaining fastener wire 34 in its deformed or open position. In the unlocked position, ball 38 is released from the notches, thereby allowing the coil 26 to expand, which causes the fastener wire 34 to close. The closure conformation of the wire may be characterized by any of those described above with reference to Figs. 3-6, for example.

Movement of the release mechanism to the open position is accomplished by applying a compressive force to the shrink tube 110 and bundle of strands 106, as shown in Figs. 9D and 9E. Advantageously, the compressive force may be applied at any opposing locations around the circumference of the shrink tube as long as the implement applying the force is oriented at an angle to the strands, preferably substantially perpendicular thereto, to allow the implement to traverse the strands so as to deform the positions thereof when the force is applied. For example, needle holder 111 could be rotated 90° (or virtually any other angle) with respect to the strands 106 as shown in the plane of the drawing, while retaining the capability of deforming the strands to an open position upon application of a compressive force. The compressive force is preferably applied using a standard needle holder 111 or forceps, although other tools could be used, preferably those with applicators narrower than the length of the shrink tube 110. As shown, the strands or wires 106 get distorted from their circular configuration under the compression. This change in shape stretches the shrink tube 110 from a circular configuration to a somewhat elliptical configuration, and removes some of the notches 109 from contact with ball 38, thereby permitting removal of ball 38 from within the chamber previously formed by notches 109 in the closed position.

Referring to Fig. 9F, release mechanism 23c also may be used to releasably couple the other end of the fastener to another flexible member such as

flexible member 19, which in turn, is coupled to a needle such as needle 17 as shown in Fig. 1. In this arrangement, a member or stopper 115, which may be annular, is secured to the other end of the fastener or wire 34 to prevent enlarged portion 36 from passing through the compression spring upon release from release mechanism 23c. Other release mechanisms, which provide synchronized release of both needles illustrated in Fig. 1, also can be used.

Figs. 10A-10F illustrate synchronized fastener release systems. Referring to Figs. 10A-10C, a first synchronized release system is shown in a coupled and decoupled state, respectfully. Although one release mechanism is shown as corresponding to release mechanism 28c, release mechanisms 28a or 28b or any release mechanism which releaseably couples the flexible member or needle to the surgical fastener and effects compression of coil 26 also may be used. At the other end of the fastener or wire 34, a release mechanism which responds to the compressive state of coil 26 and releases the fastener or wire 34 upon release of compressive forces on the coil is shown and generally designated with reference numeral 29a. Release mechanism 29a comprises two members 121 each having a recess 122 formed therein and arranged to form chamber 124 when members 121 are aligned as shown in Fig. 10A. Recesses 122 are configured to retain enlarged portion 36, which is shown with a cylindrical configuration, but may have a spherical or other suitable shape for operatively associating with a suitably configured chamber. Further, members 121 may have semicircular transverse cross sections or some other combination of transverse shapes that can collectively provide the desired chamber to retain enlarged portion 36. The number of members 121 also may vary as would be apparent to one of ordinary skill.

Release mechanism members 121 have tapered ends 126, which are configured for positioning between coil 26 and fastener wire 34 as shown in Fig. 10A. When tapered ends 126 are so positioned and coil 26 is in a compressed state, coil 26 holds tapered ends 126, which are normally biased away from each other as shown in Fig. 10C, sufficiently together to retain enlarged portion 36 within chamber 124. When release mechanism 28c is actuated (e.g., radially

compressed) to release enlarged portion 38 of fastener wire 34, coil 26 assumes its relaxed state, thereby releasing tapered ends 126 of release mechanism 29a from the coil and allowing the tapered ends to radially expand and release enlarged portion 36 of fastener wire 34 as shown in Fig. 10C. Accordingly, both needles and flexible members may be decoupled from the fastener when release mechanism 28c is actuated.

Figs. 10D-10F show another synchronized fastener system which is the same as the system shown in Figs. 10A-10C with the exception of release mechanism 29b and the cooperating portion of the fastener or wire 34 being substituted for release mechanism 29a. In this embodiment, an annular member or stopper 115, which may be annular, is slidably coupled to fastener wire 34. Member 115 is configured to resist passage of coil 26 thereover. Accordingly, member 115 may have an outer diameter slightly greater than at least the portion of the coil adjacent thereto. A tapered or frustoconical member 3' is secured to an end of fastener wire 34, which need not include an enlarged portion. Member 3' is the same as member 3 with the exception that member 3' has a channel 134 for receiving flexible member or suture 19. Channel 134 extends radially outward from bore 132, which is formed through member 3', for receiving the fastener or wire 34.

Flexible member 19 is threaded through channel 134 and between tapered member 3' and annular member 115. When coil 26 is in a compressed state as shown in Fig. 10D, the coil urges member 115 toward tapered member 3' and compresses flexible member 19 therebetween. In this manner, flexible member 19 is secured to the fastener or wire 34. When release mechanism 28c is actuated (e.g., radially compressed) to release enlarged portion 38 of the fastener or wire 34, coil 26 assumes its relaxed state so that annular member 155 may slide away from tapered member 3' and release flexible member 19. Accordingly, both needles and flexible members may be removed from the fastener when release mechanism 28c is actuated. Although a metal flexible member may be used, a polymeric flexible member may be preferred.

Figs. 11A and 11B show another release mechanism generally indicated with reference numeral 29c. Release mechanism 29c includes a sleeve 142, which is slidably mounted over flexible member 19 so that it can be positioned over the flexible member and the fastener or wire to releaseably hold the flexible member and the fastener together. The end portion of the flexible member opposite the needle and the end portion of the fastener or wire to be engaged therewith may be configured to provide interlocking engagement therebetween. In the embodiment shown in Figs. 11A and 11B, the flexible member, which preferably is metal in this example, and the fastener or wire end portions have mating flange and groove configurations. Flexible member 19 includes groove 144a and flange 146a, which mate with or interlockingly engage groove 144b and flange 146b, which are formed in wire 34. When sleeve 142 is moved away from the fastener or wire, the coupling becomes unrestrained and the flexible member and the fastener or wire can be readily separated by removing flanges 146a and 146b from grooves 144a and 144b as shown in Fig. 11B. Member 115 may be secured to fastener wire 34 to prevent the end of coil 26 adjacent to groove 144b and flange 146b from sliding thereover. Member 115 also may be described as a stopper for spring 26.

Figs. 12A and 12B show another release mechanism, which is generally designated with reference numeral 29d. In this embodiment, tapered member 3 is provided with a bore for receiving both flexible member 19 and the fastener or wire 34. Member or collar 115 may be fixedly secured to the fastener or wire 34 to resist coil movement over the wire and toward the flexible member. The fastener or wire also may be fixedly secured to the inner wall of tapered member 3 by, for example, gluing or welding. One end of the flexible member is tied into a knot such as knot 150. The knot is packed into the bore 152 and the tapered member is swaged or crimped as shown in Figs. 12A and 12B to secure the knot in the bore. The flexible member is cut as shown in Fig. 12B to decouple the flexible member from the fastener.

Figs. 13A and 13B illustrate a further release mechanism , which is generally designated with reference numeral 29e. Release mechanism 29e

generally comprises a release member having a cavity formed therein to receive the fastener or wire 34 and a portion configured for severing the fastener wire. This advantageously eliminates the need for a separate cutting tool to separate the suture or needle from the fastener. One example of such a release member is shown as release member 160. Release member 160 has one end which is fixedly secured to tapered member 3 to which flexible member 19 is secured. Alternatively, members 3 and 160 may be integrally formed. Release member 160 is configured to form a cavity 162 therein and may be in the form of a sleeve. Member 160 includes annular flange 164 through which fastener wire 34 is received. Annular flange 164 includes an annular lip 166, which forms a cutting surface or annular blade. Release member 160 also may include an opening for receiving flexible member 19 therethrough as shown in Figs. 13A and 13B. In this example, release member 160 can be fixedly secured to flexible member 19, which, in turn, can be fixedly secured to tapered member 3. Of course, it should be understood that members 160 and 3 can be directly secured to one another or integrally formed as a single piece. When release member 160 is radially compressed as shown in Fig. 13B, annular lip severs fastener wire 34 and decouples flexible member therefrom. Fastener wire 34 may be provided with annular groove 168 to enhance wire fracture. Release member 160 or annular lip 166 may be 400 series stainless steel or tool steel to facilitate hardening. Other materials that tend to provide an effective cutting tool also may be used. Release member 160, however, should comprise material that provides the desired flexibility. Further, it should be understood that although release member 160 is shown with a generally cylindrical configuration, other configurations may be used. In assembly, member 115, which may be annular, may be swaged, glued or welded to wire 34 to compress coil 34 after the other end of wire has been secured to a locking device or coupling so that the fastener opens as may be done in the embodiments of Figs. 11A and B and 12A and B. Wire 34 may be preformed with groove 168 or the groove formed prior to sliding member 160 over wire 34 so as to engage blade 166 with the groove.

It is to be understood that locking devices other than those described above may be used without departing from the scope of the invention. For example, a locking device (not shown) may comprise a tubular member having an opening formed in a sidewall thereof for receiving an end portion of the wire. The end of the wire may be bent so that it is biased to fit within the opening in the sidewall of the tubular member. An instrument, such as a needle holder may then be used to push the wire away from the opening in the tubular member and release the wire from the tubular member. Various other types of locking devices including a spring detent or bayonet type of device may also be used. Further, the fastener or wire end portions may be configured differently than that shown. For example, one or both of the fastener or wire end portions may be provided with grooves instead of enlarged portions and the release mechanisms or locking device arms, such as, for example, fingers 81 or strands 106, may be provided with projections to releaseably engage with the grooves.

Fig. 14A is a front view of a another embodiment of a tissue connector assembly of the present invention which is generally designated with reference numeral 211. Tissue connector assembly 211 is the same as tissue connector assembly 11 with the exception that locking device or release mechanism 28 is directly connected to needle 16. Although any of the release mechanisms 28a-c may be used to couple the fastener to needle 16, release mechanism 28c is shown in Fig. 14B for purposes of illustrating a connection between a locking device and needle 16.

Referring to Fig. 14B, rod 162 extends from needle 16. Rod 162 and needle 16 may be integrally formed or be separate elements secured which are fixed to one another. The coupling of strands 106 to the needle is preferably accomplished by gluing or soldering to the rod 162, although other equivalent or similar known joining techniques may be employed (e.g. welding, threadably attaching, etc). Similarly, when the rod and needle are discrete elements, the rod is preferably glued, soldered or threaded into the needle. Alternately, rod 162 may extend from or be affixed to a transition element which in turn is affixed to needle 16.

Fig. 15 is a front view of a lateral tissue connector which is generally designated with reference numeral 300 and which can be used in conjunction with any of the assemblies described above as will be described in detail below. Tissue connector assembly 300 generally includes needle 16, a locking device or release mechanism, and a fastener, which may be fastener 20, 40, 41, or 43, for example. In this embodiment, needle 16 is attached directly to a locking device, such as locking device 28c, a connection for which is described above with reference to Fig. 14A. Fig. 14A shows tissue connector assembly 211 with the fastener in its open (deformed) configuration.

As noted above, tissue connector assemblies described above have many uses. They may be especially useful for minimally invasive surgical procedures including creating an anastomosis between a vascular graft 12 and an artery 14. The anastomosis may be used to replace or bypass a diseased, occluded or injured artery. A coronary bypass graft procedure requires that a source of arterial blood flow be prepared for subsequent bypass connection to a diseased artery. An arterial graft may be used to provide a source of blood flow, or a free graft may be used and connected at the proximal end to a source of blood flow. Preferably, the source of blood flow is one of any number of existing arteries which may be dissected in preparation for the bypass graft procedure. In many instances it is preferred to use the left internal mammary artery (LIMA) or the right internal mammary artery (RIMA), for example. Other vessels which may be used include the saphenous vein, gastroepiploic artery in the abdomen, radial artery, and other arteries harvested from the patient's body as well as synthetic graft materials, such as DACRON® (polyester fibers) or GORETEX® (expanded polytetrafluoroethylene). If a free graft vessel is used, the upstream end of the dissected vessel, which is the arterial blood source, will be secured to the aorta to provide the desired bypass blood flow, as is well known by those skilled in the art. The downstream end of the graft vessel is trimmed for attachment to an artery, such as the left anterior descending coronary (LAD). It is to be understood that the anastomosis may be formed in other vessels or tissue.

Figures 16A-16D diagrammatically illustrate a method of aligning and connecting graft and target vessels, such as connecting a graft vessel 12 to an artery 14 (target vessel) using tissue connector assemblies 11 and 300. In this example, two tissue connector assemblies 11 are used to make connections at generally opposite sides of the graft vessel and tissue connector assemblies 300 are used to make connections between those made with assemblies 11. The procedure may be accomplished with a beating heart procedure with the use of a heart stabilizer to keep the heart stable, for example. The procedure may also be performed endoscopically. It also should be understood that tissue connector assemblies 211 may be substituted for assemblies 11.

The patient is first prepped for standard cardiac surgery. After exposure and control of artery 14, occlusion and reperfusion may be performed as required, an arteriotomy is performed on artery 14 to provide an opening 120 for receiving a graft vessel. After the snared graft vessel 12 has been prepared as would be apparent to one of ordinary skill in the art, a tissue connector assembly 11 is attached to the free end of the graft vessel along an edge margin of the vessel. In order to attach the connector assembly 11, the surgeon grasps needle 16 with a needle holder (e.g., surgical pliers, forceps, or any other suitable instrument) and inserts needle 16 into the tissue of graft vessel 12 in a direction from the interior of the vessel to the exterior of the vessel. The surgeon then releases the needle 16 and grasps a forward end of the needle which is now located outside graft vessel 12 and pulls the needle and a portion of suture 18 through the vessel. Needle 17 is passed through opening 120 formed in the sidewall of the artery 14 and inserted into the tissue of the artery in a direction from the interior of the artery to the exterior of the artery. The surgeon then grasps needle 17 located outside the artery 14 and pulls the needle and a portion of suture 19 through the arterial wall. A second tissue connector assembly 11 may be inserted as described above at a location generally 180 degrees from the location of the first tissue connector in a conventional "heel and toe" arrangement.

Once the tissue connector assemblies 11 are inserted, graft vessel 12 is positioned above and aligned with opening 120 in the sidewall of the artery 14

(Fig. 16A). A section of each assembly is located between graft vessel 12 and artery 14. The needles 16 and 17 are pulled generally away from the artery 14 to reduce the length of the sutures 18 and 19 (eliminate slack of the sutures) between vessel 12 and artery and "parachute" the vessel onto the artery (Fig. 16B). The needles 17 are then pulled away from the artery 14 until each fastener 20 is positioned within the target vessel 14 as shown in Fig. 16B. Needles 16 are then pulled away from graft 12 until the fasteners are positioned with one end of each fastener 20 extending from the vessel and the opposite end of each fastener extending from the artery (Fig. 16C). The edges of the graft vessel 12 and artery 14 are positioned adjacent one another to form a continuous interior and exterior surface along the mating portions of the vessel and artery. As shown in Fig. 16F, the tissue is compressed within the fastener 20.

A surgical instrument (e.g., needle holder) is used to radially squeeze each locking device 28 to release the locking device from the fastener 20. Upon removal of each locking device 28, each coil 26 moves to its free uncompressed state which allows fastener wire 34 to return to its original undeformed closed position (Fig. 16D). As the wires 34 move to their closed position the adjacent tissues of the graft vessel 12 and artery 14 which were previously pulled together during the parachuting of the graft vessel onto the artery, are squeezed together to securely engage the graft vessel and artery (Figs. 16E and 16F). It should be noted that as each locking device 28 is squeezed at least two steps are accomplished. The fastener 20 is released from locking device 28, thus allowing coil 26 to uncompress and the wire 34 to move to its closed configuration, and the needle 16 is released from the fastener. Thus, any of the locking devices 28 described above provides for simultaneous actuating closure of the fastener 20 and release of the needle 16 from the fastener. Further, radially compression of release mechanisms 29 releases needles 17 and sutures 19 from the fasteners. However, if one of the synchronous release systems described with reference to Figs. 10A-10F is used, radial compression of a locking device 28 device will effect essentially simultaneous closure actuation of a respective fastener and release of needles 16 and 17 and sutures 18 and 19.

The tissue connector assemblies 300 are subsequently inserted at circumferentially spaced locations around the periphery of the graft vessel to sealingly fasten graft vessel 12 to artery 14. Needle 16 of fastener 300 is inserted into graft vessel 12 from the exterior surface of the graft vessel and pushed through the graft vessel and artery 14 tissue. The needle holder is then used to pull the needle 16 through the arterial wall. An instrument (same needle holder or other suitable instrument) is used to apply a squeezing force to the locking device 28 to release fastener 20 from needle 16. This allows coil 26 to move to its uncompressed configuration and the wire to move to its closed position. It should be noted that the tissue connector assemblies 11 may remain with their fasteners in their open position while tissue connector assemblies 300 are inserted into the tissue and moved to their closed position. The locking devices 28 of the tissue connector assemblies 11 may subsequently be removed from the fasteners 20 to allow the fasteners to move to their closed position. The number and combination of tissue connectors assemblies 11 and 300 required to sealingly secure the connecting tissues together may vary. For example, only tissue connector assemblies 11 may be used to complete the entire anastomosis.

Although coils 26 are shown remaining on the fastener or wire (Fig. 16D), it is to be understood that coils 26 may also be removed from wires 34, leaving only the wires in the connected tissue.

As an alternative to inserting tissue connector assemblies 11 at "heel and toe" locations described above, a number of tissue connector assemblies 11 may be inserted generally around the location of the heel. The graft vessel may then be pulled towards the artery to determine whether the opening formed in the sidewall of the artery is large enough before completing the anastomosis. It also should be understood that tissue connector assemblies 211 may be used instead of or in conjunction with assemblies 11.

Although the suturing procedure has been described for an end-to-side anastomosis, it should be appreciated that the procedure is applicable to an end-to-end and side-to-side anastomosis, connecting various tissue structures

including single and multiple tissue structures, and puncture sites, and connecting tissue to a prosthetic graft or valve, for example.

It will be observed from the foregoing that the tissue connector assemblies of the present invention have numerous advantages. Importantly, the assemblies are easier and faster to apply than conventional sutures which require tying multiple knots. The assemblies also may be used in minimally invasive procedures including endoscopic procedures.

All references cited above are incorporated herein by reference.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. The full scope of the invention is set out in the claims that follow and their equivalents. Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.